already attached prior to packaging and sterilizing as taught by '665 in order to save time. In view of the following, this rejection is respectfully traversed.

At pages four and five of the Office Action, the Examiner states that "Dumican does teach grafts and has suture material attached to the graft". The Examiner further states that the teaching relied on from Dumican is that a graft is sterilized and has suture material in the same package. The Examiner explains that one of ordinary skill would look to combine these because McGuire is silent as to whether the suture and graft are in the same package, but does mention packaging. Thus, the Examiner states, that it would be an advantage to attach the sutures and graft together prior to packaging, in that it reduces extra packaging if they were separate.

The Examiner states that McGuire '669 does not disclose a package or kit with sutures attached to the graft prior to sterilizing and packaging. Claim 1 is directed to a replacement package for the repair of a damaged ligament and requires a non-autologous graft material having a first set of sutures attached to the proximal end and a second set of sutures attached to the distal end to form a graft unit having pre-attached sutures, and the graft unit having pre-attached sutures is preserved and provided in sterile packaging. Claim 35 requires a kit including a sterile packaged prepared non-autologous replacement ligament having pre-attached sutures to form a graft unit for aiding in insertion into a patient, and a graft fixation device, where the graft unit includes attached sutures.

Contrary to the Examiner's contention, Dumican '665 does not teach a ligament replacement having sutures already attached prior to packaging and sterilizing. Rather, '665 teaches ligament replacement devices that are composed of polymeric suture material which is twisted, heated and finally braided. The braided device is cut to a desired length and capped at both ends with aluminum or silver sleeve and then over-capped with a stainless steel cap and small metal swivel pins. Needles may then be optionally attached. '665 do not teach or suggest attaching sutures to the ends of the braided device to aid in insertion. Rather, '665 requires metal end caps and optionally needles. Please see '665, Examples 6, and 7-13. In Example 6, '665 discloses that applications requiring that the implant be passed only through open joint space, or through pre-drilled tunnels in bone, that the

swivel needles would not be required and the implants may instead have either melt-fused ends to prevent fraying or ends stiffened by surrounding tubes that are melt-fused or heat shrunk onto the material of the device itself. '665 does not disclose attaching sutures prior to packaging and terminal sterilization. The Examiner states that McGuire '669 discloses at col. 5, lines 17-22, that fixation devices are used in "kits" for ligament repair. This teaching is not found. Col. 5, lines 17-22, recite "...In affixing the composite graft 80 within a bone tunnel, contact between a screw 82 and the tendon should be avoided so as not to cut or tear the tendon. To better insure that the screw is out of contact with the tendon, and interference screw should be driven along the bone portion of the graft between the graft and the bone tunnel wall..." Upon review, no teaching of a "kit" was found in '699. Clarification is requested.

McGuire '699 does not teach or suggest the presently claimed replacement package or kit where the replacement graft includes sutures attached at both ends, prior to sterilization and packaging. Dumican et al. do not cure the deficiencies of McGuire '699 since Dumican et al. do not teach or suggest a braided device having sutures attached at its ends prior to sterilization and packaging.

In view of the above, it is submitted that nothing in McGuire '699 or Dumican et al., taken alone or together, render the claimed invention obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 3 of the Office Action claims 5, 6, and 39, have been rejected under 35 USC § 103(a) as being unpatentable over McGuire ('669) in view of Dumican et al. ('665) and further in view of Schmieding '561.

The Examiner states that McGuire in view of Dumican do not disclose the use of long strand sutures and various lengths of ligaments and that Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, and that Schmieding teaches the use of various lengths for ligament repairs. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by

Schmieding for the graft of McGuire as modified by Dumican in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place. In view of the following, this rejection is respectfully traversed.

In view of the arguments presented above as to claims 1-4, 35, 36, and 38, it is submitted that Schmieding does not cure the deficiencies of McGuire and Dumican, taken alone or together, since Schmieding also does not teach or suggest a replacement ligament having sutures already attached prior to packaging and sterilizing, as required by the present claims.

In view of the above, it is submitted that nothing in McGuire '699, Dumican et al., or Schmieding, taken alone or together, render the claimed invention obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At page 3 of the Office Action claims 1-4, 35, 36, and 38, have been rejected under 35 USC § 103(a) as being unpatentable over McGuire ('669) in view of Li et al. ('942).

The Examiner states that McGuire does not disclose pre-attached sutures with the graft in sterile packaging, but that Li et al. teach a medical device used in surgery that has sutures pre-attached to the device and is provided in sterile packaging. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to move the step of pre-attaching the sutures to the graft prior to packaging as taught by Li et al. instead of pre-attaching the sutures to the McGuire graft prior to implanting such that the graft is ready to be implanted immediately once opened from the package. In view of the following, this rejection is respectfully traversed.

McGuire is discussed above. Li et al. is directed to a holder for a suture anchor having a suture coupled to the suture anchor and at least one suture needle attached to the suture. At col. 1, lines 5-8, Li et al. disclose that the invention relates to surgical anchors and fasteners, and in particular, to a surgical anchor for fastening sutures into bio-organic material. At col.1, lines 55-60, Li et al. disclose that the holder for a suture anchor with sutures and suture needles attached thereto provides for controllable release of the sutures, thereby preventing entanglement and contamination

of the sutures. Li et al. disclose at col. 4, lines 37-40, that the entire holder with the suture anchor, sutures and suture needles attached thereto is sterilized and disposed in a sterile package. At col. 4, last paragraph, Li et al. disclose that once the anchor is installed, sutures can be pulled out of the slot and will unwind from the holder, while the needles remain in the channels of the holder until they are removed by the surgeon for suturing another member to the anchor.

Li et al. do not teach or suggest an implantable ligament replacement graft. Li et al. do not teach or suggest an implantable ligament replacement graft having pre-attached sutures where the sutures are attached prior to sterilization and packaging, as required by the present claims. Li et al. do not suggest any kind of implantable graft or device to repair or replace an injured or defective ligament or tendon. Rather, Li et al. teach a device for holding sutures and instruments for suturing (needles) which device prevents tangling of the sutures during application and protects the surgical needles and sutures from external contact during the installation of the suture anchor. Li et al. require a holder for a suture anchor with the sutures and suture needle attached, where another member is sutured for example, to bone. The sterile packaged device of Li et al. is not implanted in a patient.

In view of the above, it is submitted that nothing in McGuire '699, or Li et al., taken alone or together, render the claimed invention obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

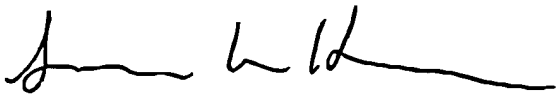
IV. At page 4 of the Office Action claims 5, 6, and 39, have been rejected under 35 USC § 103(a) as being unpatentable over McGuire ('669) in view of Li et al. ('942) and further in view of Schmieding ('561).

The Examiner states that it would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire as modified by Li et al. in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place. In view of the following, this rejection is respectfully traversed.

In view of the arguments presented above as to claims 1-4, 35, 36, and 38, it is submitted that Schmieding does not cure the deficiencies of McGuire and Li et al., taken alone or together, since Schmieding also does not teach or suggest a replacement ligament having sutures already attached prior to packaging and sterilizing, as required by the present claims.

It is submitted that the claims are in condition for allowance and early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned at her Virginia telephone number on any questions that may arise.

Respectfully submitted,
LIFENET



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Date: January 2, 2003

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